Product Development

With its manufacturing partners, the MPP continued to intensify its efforts to expedite the development of generic versions of hepatitis C and HIV medicines in 2016. The MPP worked closely with its industry partners and provided early licences and support such as technical/commercial advice, forecasts, project management and market intelligence to accelerate development of active pharmaceutical ingredients (APIs) and formulations.

The MPP also identified and engaged with new players in 2016, including Beximco and Sandoz, two generic manufacturing partners from Bangladesh and Germany respectively.

In total, the organisation signed 12 new sublicensing agreements in 2016 for three antiretrovirals and one direct-acting antiviral. As of December 2016, the MPP's 15 manufacturing partners were working on more than 100 projects to develop APIs for more than 14 formulations and seven compounds.

Paediatric HIV Treatment Initiative (PHTI)

The Medicines Patent Pool is a key partner in the Paediatric HIV Treatment Initiative (PHTI), established in 2014 by Unitaid, the Drugs for Neglected Diseases *initiative* (DND*i*), the Clinton Health Access Initiative (CHAI) and the MPP to deliver six WHO-priority formulations for children. Although the latest figures from UNAIDS suggest that treatment coverage has risen among children living with HIV (CLHIV) over the past several years, less than half of children in need receive therapy. The dearth of paediatric formulations continues to block progress in HIV treatment access.

The MPP is currently leading two important PHTI projects to improve treatment options for children and their caregivers. In collaboration with its generic partners, the organisation is spearheading the development of the WHO-recommended first-line treatment for children from three to 10 years of age, ABC/3TC/EFV, as well as the development of paediatric raltegravir, a suitable treatment for infants and young children.

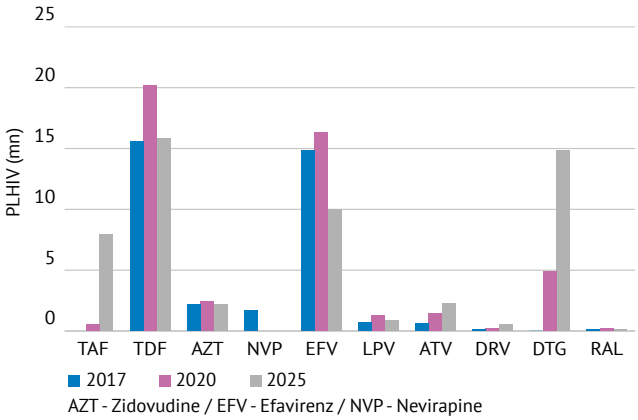
Technical Expertise

Forecasting

The MPP and the World Health Organization jointly prepare forecasts on the use of antiretroviral medicines in low- and middle-income countries. Among other analyses, these forecasts provide broad support to the HIV community and help guide MPP industry partners on access strategies, prioritisation and capacity-building. Forecasts also assist policymakers, procurement agencies, regulatory agencies and other public health stakeholders in planning policies and preparing for market uptake.

Recent forecasts published in PLOS One in 2016 concluded that DTG, licensed to the MPP from ViiV Healthcare, will likely be a major player among antiretroviral treatment regimens through 2025. TAF, licensed to the MPP from Gilead Sciences, will likely witness an increasing market share. Other currently used ARVs are expected to also play a crucial role, and their continued supply will be key to sustaining international scale-up targets. With increased access to viral load testing, substantially more people living with HIV could be using protease inhibitor-containing regimens as second-line treatment by 2025, mainly lopinavir/ritonavir and atazanavir/ritonavir. Both of these treatments are licensed to the MPP for generic manufacture and supply.

Number of People Living With HIV Using Each Antiretroviral



AZT - Zidovudine / EFV - Efavirenz / NVP - Nevirapine

Target Medicines

Over the past several years, the MPP has worked closely with the public health community to update its Antiretroviral Priority List based on recent clinical data and updated patent information. The list has sought to inform the organisation's in-licensing activities, identifying the most appropriate ARVs with the highest probability of improving public health in developing world settings. In 2016, the MPP expanded this process to include intense work on hepatitis C treatments. Among other activities, the team held consultations with civil society and disease experts at the European Association for the Study of the Liver conference in Barcelona and with HIV advocates at the International AIDS Conference in Durban. The final prioritization report will be published in 2017 and will serve as a roadmap for MPP's in-licensing strategies over the coming years.

MedsPaL
THE MEDICINES PATENTS & LICENCES DATABASE

MedsPaL - The Medicines Patents and Licences Database

On 5 October, the Medicines Patent Pool launched MedsPaL, its Medicines Patents and Licences Database, a new resource for information on the intellectual property status of priority medicines in developing countries. Introduced at the World Intellectual Property Organization (WIPO) General Assemblies, MedsPaL replaced MPP's HIV patent status database and includes patent and licensing data on HIV, hepatitis C and tuberculosis treatments covering more than 4,000 national patent applications in more than 100 low- and middle-income countries.

MedsPaL has searchable information on 35 patented medicines and more than 100 formulations for the treatment of HIV, hepatitis C and tuberculosis included in WHO guidelines or in its Essential Medicines List. The database also includes data on more than 30 licences to enable competitive manufacturing or supply of these medicines in low- and middle-income countries and on data exclusivity for 11 countries.

To support the MedsPaL initiative, the MPP signed collaborative agreements with the European Patent Office (EPO), Chile's National Institute of Industrial Property (INAPI), and the Dominican Republic's National Office of Industrial Property (ONAPI), and will be pursuing further arrangements with other patent offices in order to receive data on a regular basis for inclusion in the database.

▲ *Maximiliano Santa Cruz, the Executive Director of INAPI and Greg Perry, the Executive Director of the MPP sign a new cooperative agreement to share patent and licensing information*

▲ *From left: Pascale Boulet, MPP consultant, Esteban Burrone, MPP Head of Policy, Maximiliano Santa Cruz and Greg Perry at the WIPO General Assembly side event for the launch of MedsPaL.*

Photo: Thiru Balasubramaniam, KEI

LAUNCH OF MEDSPAL, OCTOBER

MPP, Unitaid and INAPI hosted a side event during the WIPO General Assembly to launch the MedsPaL database. The WIPO event featured an introduction from Maximiliano Santa Cruz and presentations from the MPP Executive Director and MPP staff. Wilbert Bannenberg, IDA Foundation; Peter Beyer, WHO; Rajesh Dixit, Office of the Controller General of Patents, Designs and Trademarks of India; Alejandro Roca Campañá, WIPO; Karin Timmermans, Unitaid; and Alessia Volpe, EPO, all served as panelists. The event underscored the importance of enhancing transparency of the intellectual property status of treatments for diseases that disproportionately affect developing countries.

> ***Access to comprehensive, updated patent information is essential for supplying customers worldwide and particularly those in middle-income countries. IDA Foundation has long relied on the Medicines Patent Pool for data related to HIV drugs. We welcome the launch of MedsPaL and the inclusion of hepatitis C and tuberculosis medicines in this new database.***
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> **Edwin de Voogd,** Chief Executive Officer of the IDA Foundation, a leading not-for-profit supplier of essential, quality-assured medicines and medical supplies to low- and middle-income countries.